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ON
LABORATORY OPERATIONS AT MARYLAND GENERAL HOSPITAL
BEFORE THE
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY,
AND HUMAN RESOURCES
OF THE
HOUSE COMMITTEE ON GOVERNMENT REFORM

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Chairman Souder, Representative Cummings, distinguished members of the Committee: I thank you for your invitation to appear here this morning to discuss efforts to ensure quality results from the Maryland General Hospital laboratory. The Centers for Medicare & Medicaid Services (CMS) works with a number of different entities, including state government agencies, professional associations and independent survey groups, to ensure that entities receiving Medicare payments comply with established conditions of participation for their provider type and that all laboratories in the U.S. meet Clinical Laboratory Improvement Amendments (CLIA) standards. We understand that Maryland General Hospital's lab has not fully complied with these conditions of participation. This morning I would like to first discuss CMS' general efforts at ensuring laboratory quality and then the specifics of the case in question.

CLIA BACKGROUND

In 1988, Congressional hearings concerning deaths of women from erroneously read Pap smears, and the proliferation of bench top laboratory technology into non-traditional testing sites, led to passage of CLIA. CLIA established quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. A laboratory is defined as any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, and treatment of a disease or impairment, or to assess health. CLIA is user fee funded; therefore, all

costs of administering the program must be covered by the regulated facilities, including certificate and survey costs.

Final CLIA regulations were published on February 28, 1992 and are based on the complexity of the test method; thus, the more complicated the test, the more stringent the compliance and oversight requirements. Three categories of tests have been established: waived complexity; moderate complexity, including the subcategory of provider-performed microscopy (PPM); and high complexity. CLIA specifies detailed quality standards for the latter two categories. Waived laboratories must enroll in CLIA, pay the applicable fee and follow manufacturers' testing instructions.

CMS is charged with the implementation of CLIA, including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, approving entities that test laboratory proficiency, selecting accrediting organizations and identifying states exempt from CLIA as a result of their licensure requirements. The Centers for Disease Control and Prevention (CDC) is responsible for the CLIA studies, convening the Clinical Laboratory Improvement Amendments Committee (CLIAC) and providing scientific and technical support/consultation to DHHS/CMS. The Food and Drug Administration is responsible for test categorization.

LABORATORY ENROLLMENT AND PERFORMANCE STANDARDS

To enroll in the CLIA program, laboratories must register by completing an application, pay fees, be surveyed, if applicable, and become certified. CLIA fees are based on the certificate requested by the laboratory (that is, waived, provider performed microscopy (PPM), accreditation, or compliance) and, for moderate and high complexity laboratories, the annual volume and types of testing performed. Waived and PPM laboratories may apply directly for their certificate as they aren't subject to routine inspections, unless there is a complaint. Laboratories that must be surveyed routinely; i.e., those performing moderate and/or high complexity testing, can choose whether they wish to be surveyed by CMS or by a private

accrediting organization. The biennial CMS survey process is outcome oriented and utilizes a quality assurance focus and an educational approach to assess compliance.

Labs subject to routine biennial surveys must comply with a number of CLIA requirements, including:

- Personnel: CLIA sets minimum qualifications for all persons performing or supervising moderate or high complexity lab tests.
- Proficiency testing: Labs must also participate in an approved proficiency testing program, that provides an external evaluation of the accuracy of the lab's test results. Under this requirement, three times per year, labs purchase samples from an external source (the proficiency testing provider), whose characteristics are not disclosed to the lab. The lab tests the samples with their routine patient testing and the results are returned to the testing provider to be graded. If the lab passes, they have met the CLIA standard. The results of proficiency testing for all labs in CLIA are transmitted to CMS and are monitored and maintained in a database. Proficiency testing providers are private companies, or state lab departments, that must meet certain CLIA requirements to provide testing samples to labs, and are approved by CMS annually.
- Quality control: Labs must have a process for monitoring personnel, testing equipment and the testing environment to ensure proper operation and accurate results each day.
- Quality assessment: Labs must have and follow a plan to monitor, on an ongoing basis, the overall operation of the laboratory, provide communications, and resolve problems that affect the quality of their testing.
- Cytology testing: CLIA sets special rules for cytology testing including workload limits, individualized proficiency testing and personnel standards, and quality control.

Data show that these regulations are helping. Since CLIA was implemented in 1992, quality deficiencies on clinical labs have decreased significantly. The first onsite surveys of labs revealed that up to 35 percent of labs had quality issues. At this time, less than 7 percent of 12,000 labs surveyed by CMS in a year have quality problems. We believe that our educational rather than punitive approach has facilitated improvement in lab quality. Data from our Survey

Evaluation Form show that most laboratories respond very positively to the educational, information-sharing approach to oversight and correct their problems before any deficiencies are cited or prior to imposition of enforcement actions. The quality assurance approach encourages labs to develop a plan to monitor their entire operation to identify and resolve their quality-related problems. Because survey data and proficiency testing data reflect that lab performance has improved over time, it demonstrates that labs are being accountable for preventing and correcting identified issues. When CMS finds problems during the survey, the lab is generally provided an opportunity to correct these problems prior to enforcement actions. Over the past five years, CMS has proposed enforcement action in 6,084 cases, and carried out such action in 487 instances.

OVERSIGHT AND SURVEYS

CMS contracts with state government entities to perform lab surveys. The state surveyor for Maryland is the Maryland Department of Health and Mental Hygiene. CMS' objective in developing an outcome oriented survey process is to not only determine the laboratory's regulatory compliance, but to assist laboratories in improving patient care by emphasizing those aspects that have a direct impact on the laboratory's overall test performance. CMS promotes the use of an educational survey process. The surveyor determines, based on observation of the laboratory's (past and current) practices, interviews with the laboratory's personnel and review of the laboratory's relevant documented records, whether the laboratory is meeting the requirements of the CLIA regulations to produce accurate, reliable and timely (quality) test results. The surveyor meets the objectives by employing an outcome-oriented/quality improvement type of survey process or approach, the intent of which is to focus the surveyor on the overall performance of the laboratory and the way it monitors itself, rather than on a methodical evaluation of each standard level regulatory requirement.

The quality assessment (QA) requirements of the laboratory regulations (42 CFR Part 493, Subpart K) are the appropriate guide that surveyors use for organizing their review. The surveyors select a cross-section of information, tour the facility, and observe testing and all aspects of the laboratory operation to assess the laboratory's ability to produce quality results as well as its ability to identify and correct problems. Emphasis is placed on overall laboratory

performance and the structures and processes contributing to the reliability of the testing. Since it would be impossible to review every test and every document in the laboratory, the surveyor reviews the selected cross-section of information to see if the laboratory has established and implemented appropriate mechanisms for monitoring and evaluating its practices and solving its problems. The surveyors investigate further any test areas identified as a problem but not addressed by the laboratory's QA program and any new testing and personnel since the last visit. If the laboratory is failing to monitor (or effectively monitor) its own systems, the surveyor can direct the laboratory to the requirements and the relevant sections for its particular setting, thereby accomplishing the educational aspect of the survey process.

If, however, problems identified during the survey, or as the result of a complaint, are not remedied in a reasonable amount of time, CMS will impose various sanctions against the labs. These may range from onsite monitoring, fines, or loss of Medicare reimbursement, to revocation of their certificate, depending on the seriousness and pervasiveness of the problem. Most laboratories correct their problems as a result of the education they receive following the survey, prior to having sanctions imposed. Only about one percent of laboratories surveyed each year have had enforcement actions taken against them. The names of these labs and the laboratory director are compiled annually and this list is placed on the CLIA web site at: www.cms.hhs.gov/clia. The 2002 registry (the most current available) lists 133 entities, 7 of them hospitals. The bulk of laboratories experiencing enforcement actions that year were physician office labs (74) and independent labs (39). The numbers of labs experiencing enforcement actions are proportional to the total number of labs of that type that are enrolled in the CLIA program.

As mentioned previously, labs that are subject to biennial surveys can choose to obtain CLIA certification by the State agency, as an agent of CMS, or by an approved private accreditation organization. Accrediting organizations with standards that are equivalent to, or more stringent than CLIA, currently approved by HHS for this purpose include: the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the College of American Pathologists (CAP), COLA (formerly Commission on Office Laboratory Accreditation), the American Association of Blood Banks (AABB), the American Society for Histocompatibility and

Immunogenetics (ASHI), and the American Osteopathic Association (AOA). States that have lab licensure program standards equivalent to, or stricter than those of CLIA can apply for "approval" or "exemption." Then the labs in these states that meet state licensure requirements are deemed to be in compliance with CLIA. There are only two exempt states at this time – New York and Washington. Additionally, there are 13 states that have a state laboratory licensure program and in these cases, laboratories within the state must comply with both CLIA and their state requirements. Maryland is one of these 13 states.

On an annual basis, CMS, through the state agencies, surveys approximately 5 percent of accredited and exempt laboratories using CLIA standards to validate that these laboratories are in compliance with CLIA by meeting the accrediting organization's standards. After surveying the accrediting organization's laboratories, CMS compares the results of the state survey to the accrediting organization's, to determine the level of disparity. The rate of disparity is the percentage of all sample validation surveys for which a State survey agency finds non-compliance with one or more CLIA conditions and no comparable condition level deficiency was cited by the accreditation organization. As set forth in regulation at 42 CFR 493 Subpart E, an accreditation program with a disparity rate of 20 percent or more is subject to a review to determine if that organization has adopted and maintains requirements comparable to those of CMS. No accrediting organization has even approached the maximum threshold of 20 percent disparity.

Complaints alleged against accredited laboratories from any source are either addressed by the accrediting organization or by the State agency in conjunction with the CMS Regional Office.

OVERSIGHT OF MARYLAND GENERAL HOSPITAL

Maryland General Hospital's laboratory is accredited by the College of American Pathologists (CAP) and is located in a state with a laboratory licensure law. Since 2002, the laboratory has had several inspections, both routine and complaint in nature. The routine biennial inspection was performed by the accrediting organization, CAP, in April of 2003. The State of Maryland conducted 2 complaint surveys, the first, for an unrelated issue, in November of 2002 as a CLIA survey for CMS and the second in 2004 as a complaint survey under their state licensure law.

The 2004 complaint survey resulted from a December 2003 complaint from a laboratory employee who alleged that machinery used in HIV and hepatitis testing was not adequately maintained and that possibly erroneous test results were provided as a result. In all of these inspections, similar issues were identified concerning the management and quality assessment processes of the laboratory that were found to be deficient. Each oversight entity addressed these issues but did not inform all of the remaining involved parties of their findings. Therefore, each oversight entity did not have the benefit of the findings of the others. Only after the December 2003 complaint to the State survey agency that pinpointed a specific problem area to investigate, and CMS recognized the severity of the issue, did all of the entities involved communicate their findings to each other. Because the exact flow of events is somewhat complex, I have included a timeline at the end of my testimony, outlining what has transpired since late 2002.

To its credit, in August of 2003, the laboratory ceased testing HIV and hepatitis C using the instrument specifically identified in the December 2003 complaint. In response to the complaint inspection conducted by Maryland under their licensure law in January 2004, the hospital began to notify several thousand patients of the need for retesting and hired a consultant firm to address the management issues in the laboratory. Testing for these conditions has not yet resumed at the lab. Specimens are being sent out to another laboratory for testing.

In addition to state licensure and CLIA requirements, hospitals that participate in Medicare and Medicaid must meet a set of conditions of participation (CoPs) in order to bill for services to these beneficiaries. The CoPs are intended to protect patient health and safety to ensure that high quality care is provided to all patients. A joint survey conducted in March 2004 by the Maryland State Agency, JCAHO, and CMS found that Maryland General Hospital was out of compliance with the CoPs for Governing Body, Quality Assessment and Performance Improvement (QAPI), and Laboratory Services.

The Governing Body CoP requires hospitals to have an effective governing body legally responsible for the conduct of the hospital as an institution. Specifically, the governing body is accountable for requirements related to medical staff, care of patients, and the institutional plan and budget.

Surveyors found that the governing body of Maryland General was not aware of problems with malfunctioning equipment, possible invalid test results, and other quality issues in the laboratory. The hospital administration failed to take any action despite events that signaled problems in the laboratory, including complaints, lost contracts with external customers, occurrence reports, and an employee blood exposure.

The Quality Assessment and Performance Improvement (QAPI) CoP requires hospitals to develop, implement, and maintain an effective, ongoing hospital-wide, data-driven QAPI program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

Surveyors found that Maryland General failed to implement and maintain an effective hospital-wide QAPI program and failed to provide adequate oversight of laboratory services. As required by CLIA, the laboratory had its own quality assurance program that reported to the hospital's QAPI program. However, hospital leadership did not provide oversight necessary to monitor the laboratory's activities and improve its performance. In fact, the hospital did not monitor the laboratory's implementation of a plan of correction based on an October/November 2002 survey by the Maryland State Agency that found numerous problems in the laboratory.

The Laboratory CoP requires hospitals to maintain, or have available, adequate laboratory services to meet the needs of their patients. The hospital must ensure that all laboratory services provided to its patients are performed in a CLIA certified facility.

Surveyors determined that Maryland General's laboratory did not meet the needs of patients. The hospital failed to follow its own procedures for ensuring safety and quality when the laboratory purchased three Adaltis Labotech™ analyzers that were used in the laboratory from June 2002 through August 2003. Surveyors found no records to show that the laboratory

informed the hospital's Clinical Engineering Department of the numerous failed runs, numerous service calls, excessive downtime, or the need for repeated training.

Because of the condition-level noncompliance, CMS notified Maryland General that the lab was no longer deemed to meet CLIA conditions by virtue of its accreditation by CAP. CMS placed the lab under the jurisdiction of the Maryland State Agency. The hospital was given ten business days to respond with a plan of correction and credible allegation of compliance (a statement that indicates a resolution of the condition-level deficiencies). Maryland General Hospital submitted the plan of correction on day 11. CMS staff is evaluating the acceptability of the plan.

Since the hospital is sending its HIV and hepatitis lab services out to a reputable party, and has addressed the management weaknesses in the lab by removing the laboratory's technical supervisor, the most serious of the condition level findings have been addressed.

If CMS is not satisfied with the plan of correction, CMS can initiate principal sanctions like revocation of the lab's CLIA certificate and cancellation of its approval to receive Medicare payment. Alternative sanctions include civil monetary penalties, a directed plan of correction, or State on-site monitoring. CMS will follow up for appropriate correction of these laboratory deficiencies through the state agency by re-visiting the laboratory on site to verify compliance.

CMS COMMUNICATION PLANS AND EFFORTS TO PREVENT RECURRANCE

When viewed in the larger context of CLIA survey work and enforcement, the problems at Maryland General Hospital are unusual in nature. Typically, the clarity of the hospital and laboratory regulations coupled with regular oversight by State surveyors, private accrediting bodies and CMS have resulted in positive results. However, as a result of this experience at Maryland General Hospital, CMS is developing a plan with tighter communication protocols to coordinate activities among the states with licensure programs, the state agencies surveying on behalf of CMS, the CMS regional offices and the accrediting organizations. CMS is also specifically addressing the communication process for complaints and accreditation organization validation surveys through its State Agency Performance Review program. These strengthened processes will be communicated through training and the re-approval process for accreditation

organizations and reflected in the State Operations Manual for the CMS regional offices and state agency surveyors. With such a plan, CMS anticipates that all parties involved in the oversight of a specific laboratory will have the benefit of the activities and timely information acquired by any of the other parties involved. This improved communication will ensure that entities performing CLIA surveys, state licensure, and private accreditation organizations are aware of complaints and deficiencies that each has found within a timeframe to prevent further exacerbation of identified problems. CMS is also considering augmenting the validation process for oversight of approved accrediting organizations to include specific data-related performance measures, and is reviewing the protocols for follow-up surveys to laboratories with significant deficiencies.

TIMELINE OF EVENTS

November 8, 2002	The State of Maryland completed a focused CLIA complaint survey from an unrelated issue that resulted in two CLIA condition level deficiencies, laboratory director responsibilities and quality assurance.
April 2003	The College of American Pathologists (CAP) conducted an accreditation survey finding minor deficiencies related to laboratory management and quality assurance.
August 2003	Hospital discontinued HIV/hepatitis testing.
December 2003	The state received a written complaint specifically addressing problems with HIV and Hepatitis C testing.
January 23, 2004	The state completed a complaint survey under their state licensure law that resulted in condition level deficiencies specific to quality control testing for HIV and Hepatitis C well as general quality assurance. The laboratory sent a plan of correction to the state.
March 8, 2004	The state notified the Philadelphia Regional Office (RO) of press interest in problems at Maryland General. The RO gave the state agency authorization to conduct a CLIA laboratory survey and a hospital Medicare investigation.
March 12, 2004	The state provided a copy of the state laboratory licensure survey performed on January 23, 2004 to the RO.
March 16-24, 2004	A joint federal CLIA and state licensure survey was conducted. The CLIA survey team, consisting of state and RO representatives, identified 6

	CLIA condition level deficiencies: bacteriology, general immunology, analytic systems, technical consultant, laboratory director and technical supervisor. The state survey agency conducting the hospital Medicare investigation and a simultaneous state licensure investigation found non-compliance with the Hospital Conditions of Participation for Governing Body, Laboratory Services and Quality Assessment and Performance Improvement Program.
April 2, 2004	The state (under their state licensure law) sent the laboratory survey findings to the laboratory.
April 5, 2004	The RO sent the survey findings and a letter to the hospital removing its hospital deemed status, placing it under state agency monitoring and requiring the hospital to submit a plan of correction for the deficiencies cited.
April 6, 2004	The Philadelphia RO sent the CLIA laboratory survey findings to the laboratory. The State and RO prepared the survey findings together, but sent separate reports. The state report was sent in response to Maryland's laboratory licensure requirements and the RO report was sent in response to the CLIA requirements. The RO report included a notice that the laboratory's accreditation deemed status had been removed and the laboratory must report directly to the state until the condition level deficiencies were removed.
April 20, 2004	Maryland General sent a plan of correction to the state.
April 22, 2004	Maryland General sent a plan of correction to the RO. The RO is currently reviewing that plan of correction. If it is not acceptable, the RO may impose civil money penalties, suspend the laboratory's CLIA certificate and/or cancel Medicare payment.
April 26, 2004	CAP conducted an inspection of the laboratory and had findings similar to CMS and the State. CAP has removed accreditation of the laboratory in the affected areas.

FUTURE EVENTS

Date TBD	State agency will perform a follow up CLIA survey to determine compliance after receiving and reviewing the laboratory's plan of correction.
Date TBD	CAP will re-visit the lab to follow-up on deficiency correction and periodically thereafter.